

# A Randomized Comparison of the Early Outcome of Stapled and Unstapled Techniques of Laparoscopic Total Extraperitoneal Inguinal Hernia Repair

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## ABSTRACT

**Objective:** The need for stapling is a relative drawback of laparoscopic hernia repairs because it adds to the complications and costs. The safety of unstapled repairs as a viable alternative lacks validation, due to the dearth of analogous comparative trials.

**Methods:** Patients were randomized to undergo either stapled or unstapled total extraperitoneal hernia repairs. The groups were matched for age and the type of hernia repaired. Pain scores, intraoperative complications, postoperative complications, postoperative recovery, and long-term outcomes (ie, groin pain, paraesthesias, testicular atrophy, and recurrence) were studied.

**Results:** The incidence of complications, pain scores, pain trends, hospital stay, return to activity, and long-term outcomes were comparable. No recurrence has been noted at a median follow-up of 23 months in 63 hernias repaired in 49 patients.

**Conclusion:** Unstapled laparoscopic hernia repair scores are equivalent to their stapled counterparts with respect to recurrence and complications.

**Key Words:** Mesh fixation, Stapling, Laparoscopic hernioplasty, TEP.

## INTRODUCTION

Surgery for inguinal hernias has undergone constant modification in surgeons' quest to achieve a perfect result. The evolution of minimally invasive surgery has instigated a redefinition of the end points of an acceptable hernia repair with a special emphasis on comfort, cost, and cosmesis, in addition to the traditional outcome measures, namely groin pain and recurrence. Thus, laparoscopic herniorraphy, with advantages related to postoperative pain, earlier return to work and normal activities, and an improved quality of life in the postoperative period has emerged as an effective alternative to open repairs. With comparable recurrence rates and complications in experienced hands,<sup>1-5</sup> cost concerns remain the main caveat in extending its benefits unhindered to the general population.<sup>6</sup>

Conventionally, in a laparoscopic hernia repair, staples or tacks are used to fix the mesh to avoid mesh migration and consequent recurrence. However, the staplers besides being expensive are also associated with complications.<sup>7-10</sup> Thus, unstapled laparoscopic hernia repair has emerged as a preferable alternative. It avoids the complications associated with stapling and has attractive economic logistics, because a significant bulk of the cost consumed in laparoscopic repairs is reflected in the need for a stapler.<sup>11-13</sup> Although isolated studies have proven the effectiveness of unstapled laparoscopic hernia repairs with the total extraperitoneal technique (TEP),<sup>9,13-15</sup> literature pertaining to this issue is meager and the incidence of recurrence remains the main concern.

The present study compares the results of stapled and unstapled laparoscopic totally extraperitoneal herniorraphy with the reference to postoperative complications, chronic groin pain, and early recurrence.

## METHODS

Patients with incomplete, reducible inguinal hernias who consented to participate in the study were randomized into 2 groups by using the sealed envelope technique as follows: Group 1 (stapled) and Group 2 (unstapled). Patients with irreducible hernias, previous lower abdominal surgery, and recurrent hernias were excluded from the

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study. The results of our study are based on our observations in 50 patients (25 in each group) who have completed a minimum follow-up of 12 months.

## Procedure

All patients underwent totally extraperitoneal laparoscopic hernia repair. We used reusable cannulas, working ports, and instruments in all cases. A polypropylene mesh 15 x 11-cm to 15 x 13-cm, depending on the patient's body habitus, was introduced and unrolled in the preperitoneal space. The mesh was positioned to cover the entire myopectineal orifice from symphysis pubis in the midline to anterior superior iliac spine laterally. Patients found to have bilateral hernias at operation underwent repair of the opposite side simultaneously. Two pieces of mesh, one on each side overlapping in the midline, were used for this purpose. Dissection of the opposite side to search for incipient hernias was not done routinely in all cases.

## Postoperative Management and Follow-up

Patients were observed in the hospital for 1 day to 2 days initially, and subsequently in the later part of the study, the procedure was done on an outpatient basis. Non-narcotic injectable analgesia (Diclofenac sodium, 50 mg every 8 hours) was given routinely to all patients in the immediate postoperative period and converted to oral as per demand dosage on the next morning. Patients were reassessed on postoperative day 7, at 1 month, and at 3 monthly intervals thereafter.

The following parameters were evaluated:

1. Pain was evaluated with the visual analog score and by the number of cases requiring analgesics for more than 1 week. Chronic groin pain was defined as pain lasting for more than 8 weeks that occurred in the vicinity of repair or along the endangered nerve territory and required analgesia or hindered physical activity. Patients were examined preoperatively and postoperatively; pain sensations, numbness, and parasthesias were assessed to rule out nerve injury;
2. Seromas and hematomas were assessed by clinical examination and noted;
3. Routine activity was defined as normal daily activities like walking, climbing stairs, bathing and other such activities;
4. Recurrence was evaluated at regular intervals by clinical examination.

## Statistical Analysis

Our data were not normally distributed, so analysis was done using nonparametric tests for 2 independent samples (Wilcoxon rank sum test) and the chi-square test. Repeated measures, such as pain trends, were evaluated using 2-way ANOVA.

## RESULTS

The group statistics of the 2 groups are shown in **Table 1**. Sixty-three hernias were repaired. Nine patients underwent bilateral hernia repair in the stapled group, and 4 in the unstapled group. Of the 9 bilateral stapled repairs, 2 patients diagnosed with unilateral hernias initially were discovered as having small contralateral hernias after insufflation of CO<sub>2</sub>. Both patients had been previously randomized to undergo stapled repair and underwent simultaneous repair of the contralateral hernia. The operation was completed successfully in all patients with no conversions. No procedure-related mortality occurred. We did not have any major intraoperative complications; however, minor complications included 2 peritoneal tears sutured intraoperatively and rupture of the balloon during initial dissection that occurred in 2 patients with the balloon being retrieved through the port under direct vision. Two patients developed subcutaneous emphysema, one in each group,

<b>Table 1.</b> Comparative Analysis of Mean Values of Parameters in the 2 Groups and Their Significance		
Parameter	Mean (Stapled; Unstapled*)	P Value (2-Tailed Test)
Age	46.40±15.19; 47.16±16.40	.961
Symptom Duration (mos)	15.71±25.53; 14.96±17.53	.593
Duration of analgesics (wks)	1.16±0.37; 1.08±0.28	.389
Post op stay (days)	1.64±0.95; 1.12±0.60	.027
Pain score day 0	2.92±2.38; 2.28±1.81	.348
Pain score day 1	1.52±1.64; 1.00±1.12	.387
Pain score day 7	0.32±0.69; 0.20±0.65	.438
Return to activity (days)	2.68±1.63; 2.12±1.51	.112
Follow-up in months	27.47±8.64; 23.98±9.9	.171
*One patient in the unstapled group was lost to follow-up 3 months after the operation.		

which resolved spontaneously after a few hours. One patient incurred an accidental urethral injury as a consequence of dislodgment of the urinary catheter during transportation. No significant difference existed in the postoperative pain scores, pain trends, and duration of analgesics required, return to activity or hospital stay. No cases of established wound infection occurred. Four patients (3 in the unstapled and 1 in the stapled group) developed seromas. The median postoperative hospital stay was 24 hours. No patient had chronic groin pain, neuralgias, or testicular atrophy. No recurrences were noted at a mean follow-up of 25.76 months (median,  $23.2 \pm 9.3$ ). The median follow-up was 27.46 months in the stapled group and 20.3 months in the unstapled group, whereas the mean follow-ups were  $27.47 \pm 8.64$  and  $23.98 \pm 9.9$ , respectively, with no significant difference. One patient expired 2 years after hernia repair due to myocardial infarction, and another was lost to follow-up early in the study (after 3 months) both in Groups 2. One patient in the stapled group developed a contralateral hernia 2 years after the initial operation.

## DISCUSSION

Mesh fixation in the laparoscopic preperitoneal repair of inguinal hernias is currently a debatable issue. In most reported trials, surgeons have unquestionably adhered to the principle of fixing the mesh on the premise that good fixation of the mesh is critical for preventing mesh migration and early recurrence. However, their judgment is based on evidence in noncomparative retrospective analyses.<sup>16</sup> Stapling has been the commonly used method of mesh fixation. But staplers are expensive and have been cited as a source of distressing and at times serious complications like nerve injuries, osteitis pubis, and other such anomalies.<sup>7-10,17</sup> Moreover, consensus regarding the number of staples and the ideal sites for their placement is lacking. Ten staples have been suggested as essential by investigators based on experimental evidence.<sup>18</sup> The transversalis fascia, rectus muscle, Cooper's ligament, and the pubic bone have emerged as the traditional safe points of fixation with avoidance of infero-medial and infero-lateral anchorage that is fraught with dangerous complications.<sup>7,17-19</sup> Others have reported lack of fixation at inferior lateral and medial sites as a prime cause of recurrence.<sup>20</sup> Adhesive glues and fibrin sealants have been tried as alternatives to stapling but the efficacy of these procedures remains to be established.<sup>21</sup>

Proponents of the open preperitoneal repairs do not recommend mesh fixation.<sup>22</sup> The justification stems from the

observation that a large mesh that satisfactorily overlaps the entire myopectineal orifice and all potential sites of herniation does not require fixation as it retains its position in the preperitoneal space by virtue of the higher intraabdominal pressure at the end of the operation.<sup>22</sup> So, laparoscopic repairs need not be different. In an endeavor to establish the fate of an unfixed mesh in the preperitoneal space in a patient undergoing transabdominal preperitoneal repairs (TAPP), Irving et al<sup>19</sup> demonstrated that a nonfixed mesh radiologically marked with clips did not appreciably migrate in follow-up x-rays even after 3 months. The first published reference to the unstapled laparoscopic technique for inguinal hernia can be traced to as early as 1994.<sup>23</sup> Thereafter, the technique has been rarely investigated, and literature pertaining to the procedure is sparse. Based on evidence in the existing retrospective and noncomparative trials, unstapled TEP repairs have been thought to have a low incidence of recurrence and complications.<sup>9,14</sup> The only published randomized study comparing stapled and unstapled TEP repairs<sup>12</sup> found no difference in recurrence rates in either group after a median 12-month follow-up.

In our study, although the mean early pain scores and duration of analgesic intake was marginally higher in the stapled group, the difference was not statistically significant. Adverse long-term outcomes, namely chronic groin pain, were not seen in either group. Although Khajanchee et al<sup>9</sup> reported an increased risk of neuropathic complications in the stapled group, other authors<sup>12</sup> have not reported any significant increase in the incidence of such complications. As increased chronic pain after stapled repairs is usually due to improper placement of staples or tacks, care should be taken during placement of staples to avoid these complications.

It has emerged from the available literature that recurrence after laparoscopic totally extraperitoneal hernia repair is most likely because of a failure in surgical technique, and causes other than fixation, such as an incomplete dissection of the myopectineal orifice or mesh size, may be important determinants.<sup>16,24</sup> Whereas a small mesh can contribute to recurrence due to incomplete coverage of the myopectineal orifice, a large mesh in an inadequately dissected space can get furled or wrinkled and result in a similar consequences. It merits consideration that inadequate mesh size might have been the prime contributor to recurrences in studies where lack of mesh fixation has been thought to be the cause of recurrence.<sup>24</sup> Experimental studies have suggested that an overlap of 3 or more centimeters is essential in preventing recurrences.<sup>25</sup> A mesh size of 10x15 cm is recommended

in laparoscopic repairs without fixation.<sup>19</sup> In our series, a standard of 15x11-cm or 15x13-cm prolene mesh was used depending on the body habitus, which ensured a wide overlap of the myopectineal orifice.

Inadequate follow-up has been the criticism voiced against these studies, and it has been emphasized that results of laparoscopic hernia repair should be reviewed after reports of adequate long-term follow-up are available.<sup>26</sup> However, unlike the tissue repairs where recurrences are reported equally in subsequent years, virtually all laparoscopic recurrences occur early, (ie, in the first year) and are due to surgeon-related factors.<sup>27</sup> This is reasonable if one is to consider mesh migration or displacement as the cause for recurrence.

The cost of the stapler is the major deterrent in extending the benefits of laparoscopic hernia repair unhindered to the general population. The results of our study are encouraging and can have an important impact on the use of laparoscopic procedures for hernia repair in a developing country like ours where most of our patients come from the lower socioeconomic strata and are often unable to bear the cost of a stapler.

## CONCLUSION

Unstapled laparoscopic totally extraperitoneal inguinal hernia repair yields equivalent results in terms of complications and early recurrence when compared with results with the stapled technique, and the unstapled procedure merits evaluation in a larger study population.

## References:

1. Felix EL, Harbertson N, Vartanian S. Laparoscopic hernioplasty: significant complications. *Surg Endosc.* 1999;13(4):328–331.
2. Ferzli G, Sayad P, Huie F, Hallak A, Usal H. Endoscopic extraperitoneal herniorrhaphy. A 5-year experience. *Surg Endosc.* 1998;12(11):1311–1313.
3. Liem MS, van der Graaf Y, van Steensel CJ, et al. Comparison of conventional anterior surgery and laparoscopic surgery for inguinal-hernia repair. *N Engl J Med.* 1997;336(22):1541–1547.
4. McCormack K, Scott NW, Go PM, Ross S, Grant AM, EU Hernia Trialists Collaboration. Laparoscopic techniques versus open techniques for inguinal hernia repair. *Cochrane Database Syst Rev.* 2003;(1):CD001785.
5. Memon MA, Cooper NJ, Memon B, Memon MI, Abrams KR. Meta-analysis of randomized clinical trials comparing open and laparoscopic inguinal hernia repair. *Br J Surg.* 2003;90(12):1479–1492.
6. Voyles CJ, Hamilton BJ, Johnson WD, Kano N. Meta-analysis of laparoscopic inguinal hernia trials favors open hernia repair with preperitoneal mesh prosthesis. *Am J Surg.* 2002;184(1):6–10.
7. Chevallier JM, Wind P, Lassau JP. Damage to the inguino-femoral nerves in the treatment of hernias. An anatomical hazard of traditional and laparoscopic techniques. *Ann Chir.* 1996;50(9):767–775.
8. Eubanks S, Newman L 3rd, Goehring L et al. Meralgia parasthetica: a complication of laparoscopic herniorrhaphy. *Surg Laparosc Endosc.* 1993;3(5):381–385.
9. Khajanchee YS, Urbach DR, Swanstrom LL, Hansen PD. Outcomes of laparoscopic herniorrhaphy without fixation of mesh to the abdominal wall. *Surg Endosc.* 2001;15(10):1102–1107.
10. Kraus MA. Laparoscopic identification of preperitoneal nerve anatomy in the inguinal area. *Surg Endosc.* 1994;8(5):377–380.
11. Farinas LP, Griffen FD. Cost containment and totally extraperitoneal laparoscopic herniorrhaphy. *Surg Endosc.* 2000;14(1):37–40.
12. Ferzli GS, Frezza EE, Pecoraro AM Jr., Ahern KD. Prospective randomized study of stapled versus unstapled mesh in a laparoscopic preperitoneal inguinal hernia repair. *Am Coll Surg.* 1999;188:461–465.
13. Spitz JD, Arregui ME. Sutureless laparoscopic extraperitoneal inguinal herniorrhaphy using reusable instruments: two hundred three repairs without recurrence. *Surg Laparosc Endosc Percutan Tech.* 2000;10(1):24–29.
14. Beattie GC, Kumar S, Nixon SJ. Laparoscopic total extraperitoneal hernia repair: mesh fixation is unnecessary. *J Laparosc Adv Surg Tech.* 2000;10(2):71–73.
15. Smith AI, Royston CM, Sedman PC. Stapled and nonstapled laparoscopic transabdominal preperitoneal (TAPP) inguinal hernia repair. A prospective randomized trial. *Surg Endosc.* 1999;13(8):804–806.
16. Tetik C, Arregui ME, Dulucq JL, et al. Complications and recurrences associated with laparoscopic repair of groin hernias. A multi-institutional retrospective analysis. *Surg Endosc.* 1994;8(11):1316–22; discussion 1322–1323.
17. Sampath P, Yeo CJ, Campbell JN. Nerve injury associated with laparoscopic inguinal herniorrhaphy. *Surgery.* 1995;118(5):829–833.
18. Kathkhouda N. *Advanced Laparoscopic Surgery Technique and Tips.* London, UK: WB Saunders Company Ltd; 1998.
19. Davis CJ, Arregui ME. Laparoscopic repair of groin hernias. *Surg Clin N Am.* 2003;83:1141–1161.
20. Lowham AS, Filipi CJ, Fitzgibbons RJ Jr., et al. Mechanisms of

hernia recurrence after preperitoneal mesh repair. Traditional and laparoscopic. *Ann Surg*. 1997;225(4):422–431.

21. Katkhouda N, Mavor E, Friedlander MH, et al. Use of fibrin sealant for prosthetic mesh fixation in laparoscopic extraperitoneal inguinal hernia repair. *Ann Surg*. 2001;233(1):18–25.

22. Stoppa R, Henry X, Verhaeghe P. Repair of inguinal hernias without tension and without suture using a large dacron mesh prosthesis and by pre-peritoneal approach. A method of reference for selective indication. *Ann Chir*. 1996;50(9):808–813.

23. Vansteens CJ, Weidema WF. Laparoscopic inguinal hernia repair without fixation of mesh (prosthesis). In: Arregui W, Nagan RF, eds. Inguinal hernia, advances or controversies?. Oxford England; Radcliffe Medical Press Ltd; 1994;435–436.

24. Felix E, Scott S, Crafton B, Geis P, Duncan T, Sewell R, McKernan B. Causes of recurrence after laparoscopic hernioplasty. A multicenter study. *Surg Endosc*. 1998;12(3):226–231.

25. Knook MT, van Rosmalen AC, Yoder BE, et al. Optimal mesh size for endoscopic inguinal hernia repair: a study in a porcine model. *Surg Endosc*. 2001;15(12):1471–1477.

26. Oishi AJ, Gardiner BN, Furumoto N, Machi J, Oishi RH. Laparoscopic inguinal herniorrhaphy: the new gold standard of hernia repair? *Hawaii Med J*. 1998;57(11):700–703.

27. Liem MS, van Steensel CJ, Boelhouwer RU, et al. The learning curve for totally extraperitoneal laparoscopic inguinal hernia repair. *Am J Surg*. 1996;171(2):281–285.